



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NADA 112-048

Thomas R. Schriemer, Manager
Worldwide Animal Health Regulatory Affairs
Pharmacia & Upjohn Company
7000 Portage Road
Kalamazoo, Michigan 49001-0199

Dear Mr. Schriemer:

We refer to your Drug Experience Report dated April 29, 1999, for Hylartin-V (sodium hyaluronate) Injection, NADA 112-048. The submission includes a two page (front and back) promotional piece coded V99-215, entitled "Higher Molecular Weight = More protection for your horse's joints" and "1999 Hylartin-V VIP Program".

The promotional piece is determined to be labeling and must include full disclosure information, i.e., a reproduction of the package insert as required under 21 CFR Part 201.105 (d) of the regulations. Furthermore, the promotional piece mentions the molecular weight of Hylartin-V as 3 million Daltons but, the product label does not specify the molecular weight of the active ingredient, sodium hyaluronate. Please furnish the molecular weight specifications (mean and range) for your product.

The scientific literature supports the greater efficacy and longevity of action of higher molecular weight hyaluronic acid preparations (≥ 1 to 2 million Dalton). This may be due to hyaluronic acid weights of greater than 500,000 that stimulate synoviocytes to increase synthesis of more hyaluronic acid. What is not clear from the literature is that the higher molecular weight products may or may not be significantly superior in efficacy and longevity to the 500,000 molecular weight products. Please provide basis for making such a claim for your product.

We wish to remind you of the commitment you made when you signed the New Animal Drug Application Form, FDA-356V, that you will promote your product only in accordance with the labeling provided for in the approved application. We request that you **immediately** cease any further distribution of this violative promotional piece and in the future, refrain from promoting your product in a manner which is not consistent with the approved labeling.

If you have any questions, you may contact us at (301) 827-6642.

Sincerely yours,

A handwritten signature in black ink, appearing to be 'MS' or similar initials, written over the printed name.

Mohammad I. Sharar, DVM, MSc
Team Leader, Marketed Product Scientific
And Regulatory Review Team II, HFV-216
Division of Epidemiology and Surveillance
Office of Surveillance and Compliance